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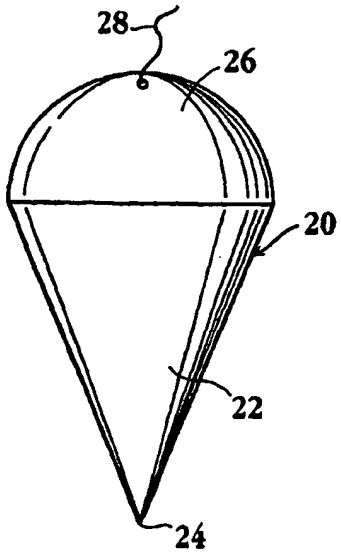
(54) Title: SPINAL FIDUCIAL IMPLANT AND METHOD



(57) Abstract: A fiducial implant for use in image-guided surgery of the spine is disclosed. The implant (20) has a tapered insertion portion (22) for inserting the implant in contact with a vertebra in the patient, a rounded head portion (26) for facilitating removal of the implant from the patient, and a flexible thread (28) attached to said insertion or head portion, for removing the implant from the patient. At least a portion of the implant is formed of a radio-opaque material. Also disclosed is a method of using such implants in an image-guided surgical procedure.

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SPINAL FIDUCIAL IMPLANT AND METHOD

Field of the Invention

The present invention relates to a spinal fiducial implant, and more specifically to a removable fiducial implant that is capable of being stably implanted in a spinal target region and easily removed (retrieved) after surgery.

Background of the Invention

A variety of diagnostic imaging techniques are available for providing high fidelity views of the human body. Non-invasive imaging systems which provide cross-section views of anatomical structure include plain view X-ray imagers, computerized axial tomography X-ray (CAT scanning) imagers, magnetic resonance (MR) imagers, positron emission tomography (PET) scanners, and ultrasound scanners.

In these imaging techniques, each set of images has a discrete, unique orientation since the images obtained will be depend on the patient's position within the imaging device. Images formed from the same imaging modality at different times and images formed at essentially the same time, but from different imaging modalities, cannot accurately be compared on a point-by-point basis. To address this problem, fiducial implants are attached to the patient in the scanned region to provide a reference frame for comparing images formed at different times and for comparing images formed from different modalities.

In addition, the use of 2D and 3D images of anatomical structures are becoming widely used in the planning of surgical procedures and during the real time performance of surgical procedures. It is crucial to establish a link between the preoperative images and the intraoperative space in order to reproduce the surgical planning accurately.

In computer assisted orthopaedic surgery, a registration process uses fiducial implants to determine the geometric correspondence between the surgical plan and the patient's bones (e.g., see U.S. Patent Nos. 5,230,338; 5,682,886; and *Clin. Orthop.* 354:49-56, 1998). Fiducial markers such as

screws (U.S. Patent no. 5,230,338), reference pins (U.S. Patent no 5,772,594) and wires (Simon et al., *Clin. Orthop.* 354:17-27, 1998) have been described for use in cranial and orthopaedic applications. For orthopedic and spinal surgery, the fiducials primarily have been used in "open" surgical procedures in which the bone is exposed during surgery and the fiducials are attached to the exposed bone surfaces.

Minimally invasive surgery is a preferred surgical method. As minimally invasive surgical procedures become more widely used, there is a need for suitable registration methods. In particular, there is a need for fiducial implants which can be implanted within or near the subsurface target site with minimal disruption or destruction of patient tissue, which will remain stably fixed at precise body positions from the time that preoperative images are taken to the time of the intraoperative procedures, and which can be easily removed from the site after surgery. These needs are particularly important in spinal surgery where the bone surfaces are located deep beneath muscle layers, and where the vertebrae of the spine are free to move during surgery.

Summary of the Invention

The present invention includes a fiducial implant for use in establishing a common, stable frame of reference for preoperative and intraoperative spinal images of a patient. The implant includes a tapered insertion portion for inserting the implant in contact with a vertebra in the patient, a rounded head portion for facilitating removal of the implant from the patient, and a flexible thread attached to the insertion or head portion, for removing the implant from the patient. At least a portion of the implant is formed of a radio-opaque material.

In various embodiments, the tapered insertion portion has a conical shape, the head portion is substantially hemi-spherical, and the insertion portion is threaded, for threaded attachment to a vertebra, and the rounded head portion is provided by structure for engaging an attachment tool. The implant has a preferred length dimension of between 3-8 mm, and a preferred width dimension between 1-5 mm.

In another aspect, the invention includes, in a method for performing

image guided surgery on a spinal target region of a patient, a method for establishing a common, stable frame of reference for preoperative and operative spinal images of the patient. The method includes implanting, at selected locations in a target region, a plurality of image-opaque fiducial implants of the type described above. The implanting step is preferably carried out by making an incision of less than 1 cm in the patient, through tissue surrounded such vertebra, and inserting the implant through the incision until it is in contact the vertebra. The implant is removed by pulling the implant by the thread until it is removed from the patient. Alternatively, the implanting may be carried out by injecting the implant through a needle directly into the target site against the bone.

These and other objects and features of the invention will be more fully appreciated when the following detailed description of the invention is read in conjunction with the accompanying drawings.

Brief Description of the Drawings

Fig. 1 illustrates a spine have a plurality of fiducial markers applied thereto;

Fig. 2 is a side view of one preferred embodiment of a fiducial implant of the invention;

FIG. 3 is a side view of another embodiment of a fiducial implant of the invention;

FIG. 4 is a side view en embodiment of the invention adapted for threaded attachment to vertebra bone;

Figs. 5A-5C illustrate the series of steps in practicing the method of the invention; and

Figs. 6A and 6B illustrate steps in practicing the method of the invention by implant injection.

Detailed Description of the Invention

Fig. 1 shows a region 10 of a patient's spine containing three vertebrae 12, 14, 16. The region shown represents a surgical target area or region intended for spinal surgery. During surgery, it is important for the surgeon to be

able to view subsurface target structures, to maximize the surgical operation steps, and minimize the risk of cutting or damaging critical nerve or vascular structures. To this end, the surgeon would like to be able to "see" hidden or subsurface structures in the region of the target. At the same time, the surgeon wishes to minimize the amount of cutting of tissue that is interposed between the surgeon and the spinal region of interest.

To optimize these aims, the surgeon can choose to perform the operation in a setting where preoperative scan images may be used to create perspective or other views of subsurface structures during the operation. The subsurface structures may be viewed, for example, from the position and orientation of a surgical tool, allowing the user to "see" what is immediately ahead of or adjacent the tip of the surgical tool, without the need to cut away any musculature or other tissue other than what is required to insert the tip of the tool to the target site. This capability, it will be appreciated, greatly minimizes the invasiveness of the surgical procedure, while providing the surgeon with an accurate view of the surgical target.

Image-guided surgery of this type has three basic requirements:

1. Preoperative scan data from the patient target site must be obtained. This is typically CT or MRI data, but may include ultrasonic or other imaging techniques.

2. During surgery, the imaging data must be placed in the frame of reference of the patient. In other words, in order to display meaningful images to the surgeon, the computer used in generating the images must know the position of the images with respect to the intraoperative position of the patient.

3. The image-guidance system must be able to place the surgical instrument in the frame of reference of the patient, so that the system computer can generate images with respect to the position and orientation of the surgical tool.

These requirements can be met by placing scan-detectable fiducials on or in a patient target region prior to collecting the scan data. The scan data then includes images of the fiducials that can then be used to reconstruct scan image in the frame of reference of the fiducials. During surgery, the same fiducials at the same positions can be used to establish a "patient" frame of

reference. The latter can be established, e.g., by intraoperative fluoroscopic imaging, to determine the coordinates of the fiducials with respect to the patient, surgical bed, or some other fixed object in the surgical theater. Once this patient frame of reference is established, the surgical tool can be placed in the same reference frame, to allow the system to generate subsurface target images as seen from a desired vantage, e.g., the tip of a surgical tool.

It will be appreciated that the above-described surgical method requires stable placement of the fiducials in the patient. In particular, the positions of the fiducials with respect to target structure must not change appreciably from the time the preoperative images are collected to the completion of the surgical technique. Since the scan data is typically collected several hours or more before actual surgery, and in any case the patient must be moved between the time of collecting scan data collection and the surgery, it is important that the fiducials be placed stably in the patient.

In surgery involving the skull, the requirement for stability of fiducial position can be achieved by securing the fiducials to the head or skull region. In spinal surgery, the problem is more difficult, because of the more difficult accessibility of vertebrae and the ability of adjacent vertebrae to move with respect to one another.

The present invention addresses the problem of stable placement of fiducials in a target region of the spine with minimal disruption or invasion of surrounding tissue, e.g., the musculature and vasculature surrounding the spine.

With continued reference to Fig. 1, the surgical target area is shown with four fiducial implants, such as implants 20 placed on two of the vertebra at the target site. These implants are imaged during image scan collection and during surgery, and are used to establish a patient frame of reference, by which a surgical tool and pre-operative scan data can be placed in a common, precisely known patient frame of reference.

Figs. 2-4 show three exemplary embodiments of an implant constructed in accordance with the invention, all in side view. The implant shown in Fig. 2, indicated at 20, includes a tapered conical insertion portion 22 terminating at a lead tip 24 and a rounded head portion 26. A thread or wire 28 is attached to

an upper end region of portion 26. The implant has a preferred length dimension of between 3-10 mm, and a preferred width dimension between 2-5 mm. The implant is formed as a unitary piece from a radio-opaque material. Alternatively, the implant may be formed of any rigid material and include a radio-opaque material either as internal structure or as a coating over a portion or all of the implant. The thread is preferably a polymer-coated wire strand, such as a nylon coated steel strand, capable of handling several pounds of strain, when the implant is pulled from its implant site.

Fig. 3 shows an implant 30 constructed according to another embodiment of the invention. The implant includes a tapered conical insertion portion 32 terminating at a lead tip 34 and a conical head portion with a rounded tip region 38. A thread or wire 40 is attached to an upper end region of the implant. The dimensions and construction of the implant are similar to those described with respect to implant 20.

Fig. 4 shows an implant 42 constructed according to yet another embodiment of the invention. As above, the implant includes a tapered conical insertion portion 44 terminating at a lead tip 48, and a conical rounded head portion 50. The insertion portion is threaded, as at 40, and the head portion is provided with an engagement slot, as at 52, to allow the surgeon to attach the implant to the bone by twisting, screw-like. A thread attached to the head is used for retrieving the implant, after a slight loosening of the screw by the surgeon. The construction and dimensions of the implant are similar to those described above for implant 20.

Figs. 5A-5C illustrate steps in the use of the implant of the invention, in accordance with one embodiment of the invention. The figures show a portion of vertebral bone 60 and a surrounding musculature 62 attached to the bone. The purpose of the method, and implant construction, is to allow stable attachment of an implant at a selected position on a vertebra, with a minimum of destruction to the surrounding musculature and/or vasculature, and also retrieval of the implant after a surgical procedure.

With reference to Fig 5A, initially the surgeon makes a small incision 64 in the surrounding tissue, This incision is preferably no wider than 1 cm, and preferably no wider than the width of the implant, and can be made with a

scalpel or the like having a selected blade width.

To place an implant, such as implant 20, at the target site, the surgeon places the implant into the incision and moves it through the incision until the lower tip of the implant is pressed against the vertebra surface, as illustrated in Fig. 5B. The surgeon may employ a grasping or guiding tool to help orient the implant during the placement process. For example, the rounded implant head may include a cylindrical channel for receiving the cylindrical tip of a guiding tool, where the tip can be easily withdrawn from the head after implant placement. Alternatively, where the surgeon uses a blunt instrument to push the tool to its placement position, the implant can be maintained in an "oriented" position by exerting an occasional tug on the thread to reposition the implant in an "upright" position.

It will be appreciated from Fig. 5B that with the implant positioned against the bone, the surrounding tissue, which has been spread to receive the implant, closes over the implant to hold it securely in place, anchored at its tip against the bone surface. Where the implant includes threaded structure, the implant may be twisted into a preformed hole in the bone, for additional anchoring to the bone.

After the preoperative and intraoperative procedures that rely on the implants, the implants are readily retrieved, as illustrated in Fig. 5C, by pulling the thread (which is accessible outside the body) to pull the implant through the incision and out of the patient.

Figs. 6A and 6B illustrates steps in placement of the implants, in accordance with another embodiment of the invention. As above, the figures show a portion of vertebral bone 70 and a surrounding musculature 72 attached to the bone. With reference to Fig 6A, initially the surgeon loads a needle 74, typically one having in inner diameter of about 0.5 -1.5 mm, with a rod-like implant 76 dimensioned for axial movement within the needle. As seen, the implant has a "lower" pointed insertion portion, and "upper" rounded portion and a thread 78 attached to implant body. In construction, both the thread and implant body can be formed as a unitary metal, e.g., stainless steel, article where the implant body is formed as a radially expanded portion of the wire.

The loaded needle is then inserted through the musculature surrounded the target bone site until the tip of the needle is against the bone. The implant is then pushed out through the needle, e.g., by a separate plunger or pusher wire (not shown) until the tip of the implant is forced against the bone. The needle is now carefully withdrawn, preferably with the pusher wire held in place to hold the implant against the bone.

Following this, and after removal of the needle and pusher wire, the tissue surrounding the implant closes around and over the implant, encasing it stably at the target site, as illustrated in Fig. 6B. After the preoperative and intraoperative procedures that rely on the implant, the implant used in the operation is readily retrieved, by pulling the thread (which is accessible outside the body) to pull the implant through the puncture path produced by the needle, and out of the patient.

From the foregoing, it will be appreciated how various objects and features of the invention are met. The implant of the invention can be placed at a target surgical site in the spinal region by insertion through a small, relatively non-invasive surgical incision or needle puncture. When placed at the target site, an implant is stably fixed at the site by virtue of its contact with or against a bone surface, and its envelopment by surrounding tissue. The implant is easily retrieved after a surgical procedure to further minimize damage to the tissue near the target site.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

IT IS CLAIMED:

1. A fiducial implant for use in establishing a common, stable frame of reference for preoperative and operative spinal images of a patient, comprising

a tapered insertion portion for inserting the implant in contact with a vertebra in the patient,

a rounded head portion for facilitating removal of the implant from the patient,

at least a portion of the implant being formed of a radio-opaque material, and

a flexible thread attached to said insertion or head portion, for removing the implant from the patient.

2. The implant of claim 1, wherein the tapered insertion portion has a conical shape.

3. The implant of claim 1, wherein the rounded head portion is substantially hemi-spherical.

4. The implant of claim 1, wherein the tapered insertion portion is threaded, for threaded attachment to a vertebra, and the rounded head portion is provided by structure for engaging an attachment tool.

5. The implant of claim 1, which has a length dimension between 3-8 mm, and a width dimension between 1-5 mm.

6. In a method for performing image guided surgery on a spinal target region of a patient, a method for establishing a common, stable frame of reference for preoperative and operative spinal images of the patient, comprising

implanting at selected locations in a target region, a plurality of image-opaque fiducial implants, each having (a) a tapered insertion portion for inserting the implant against a vertebra in the patient, (b) a rounded head

portion for facilitating removal of the implant from the patient, at least a portion of the implant being formed of a radio-opaque material, and (c) a flexible thread attached to the insertion or head portion, for removing the implant from the patient.

7. The method of claim 6, wherein said implanting includes making an incision of less than 1 cm in the patient, through tissue surrounded such vertebra, and inserting the implant through the incision until it is in contact the vertebra.

8. The method of claim 6, wherein the implanting is dimensioned to be moved within a needle, and said implant includes puncturing the tissue surrounding such vertebra with the needle, forcing the implant in the needle against the vertebra, and withdrawing the needle from the implantation site.

9. The method of claim 6, which further includes removing the implant, after such surgery, by pulling the implant by the thread until it is removed from the patient.

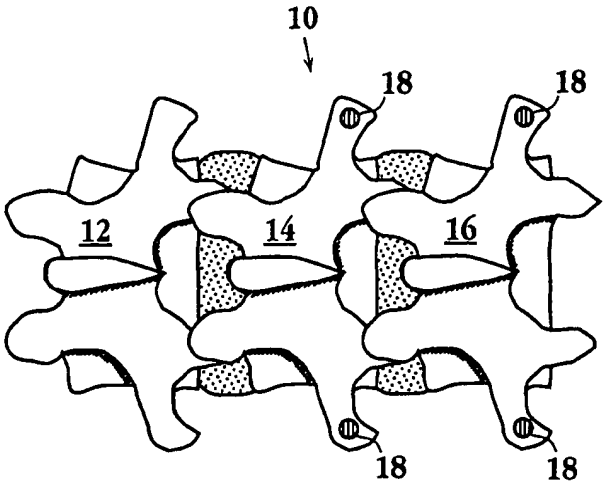

Fig. 1

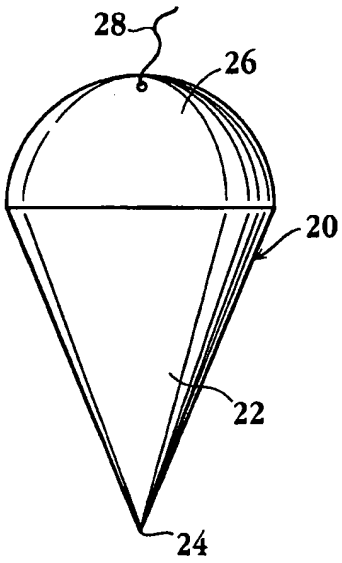

Fig. 2

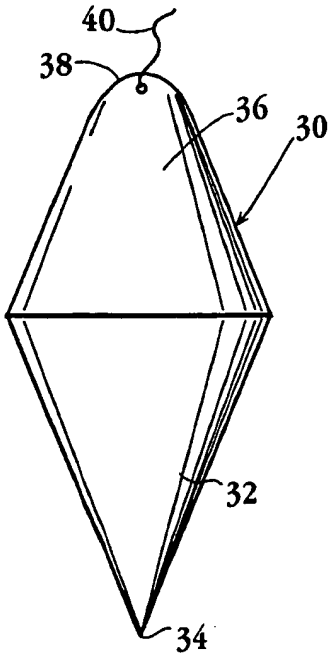

Fig. 3

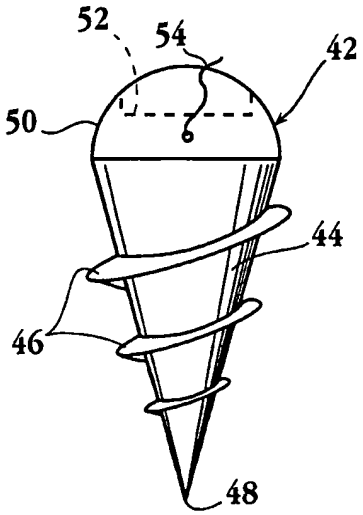

Fig. 4

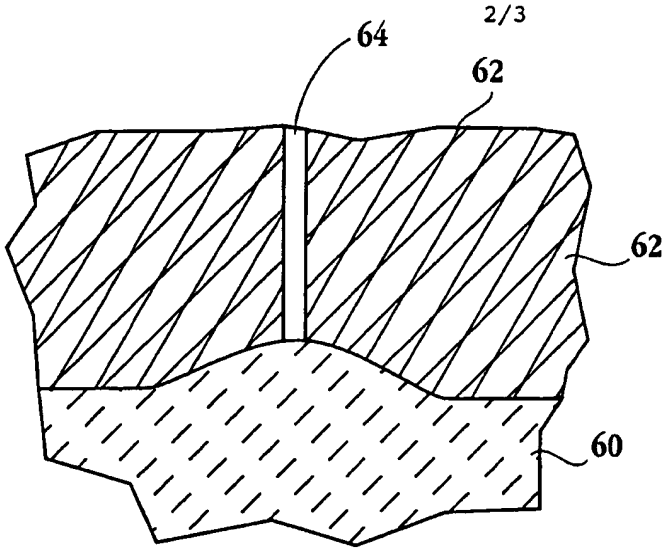

Fig. 5A

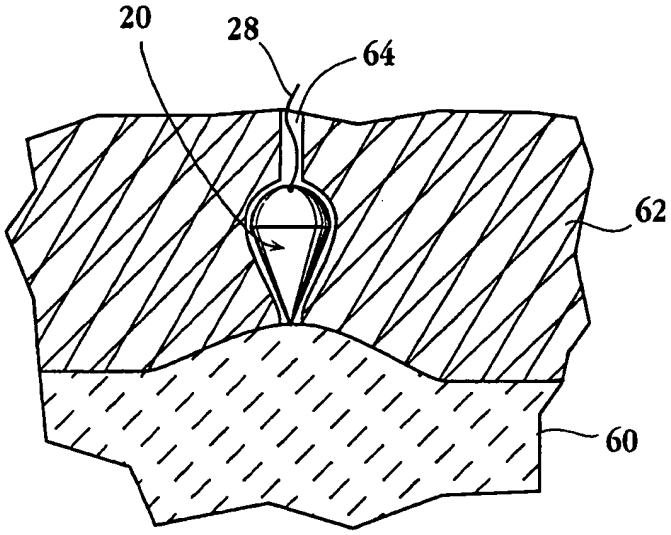

Fig. 5B

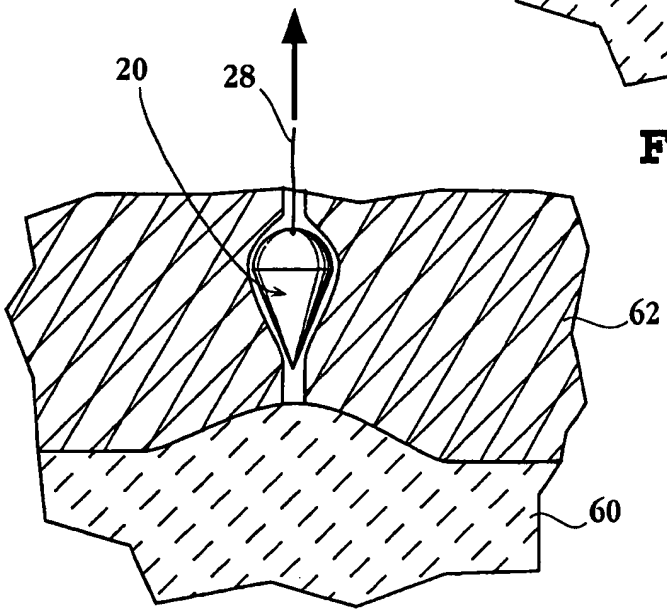

Fig. 5C

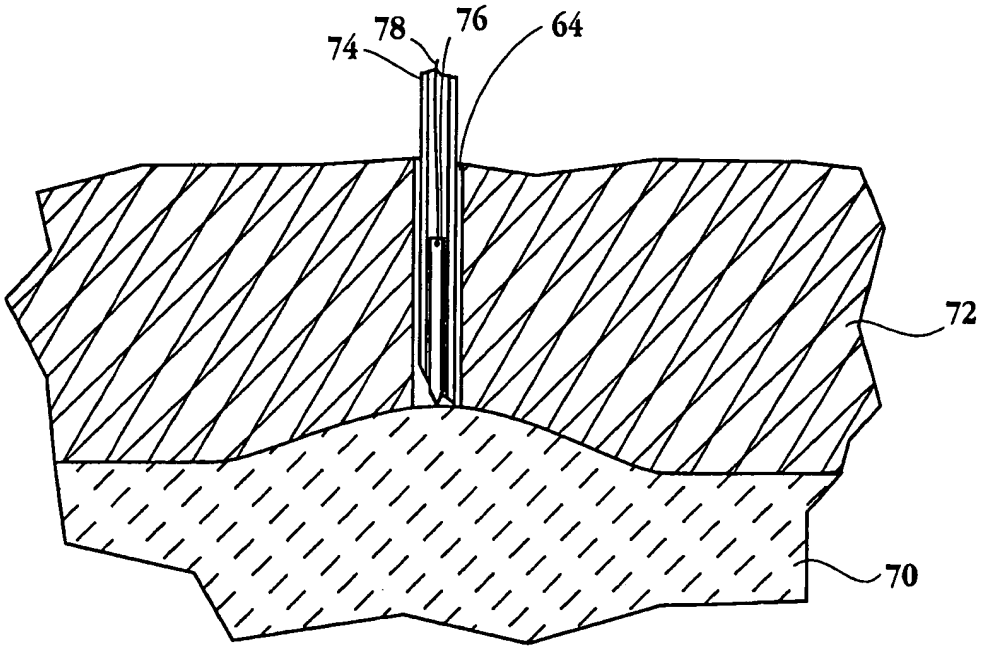

Fig. 6A

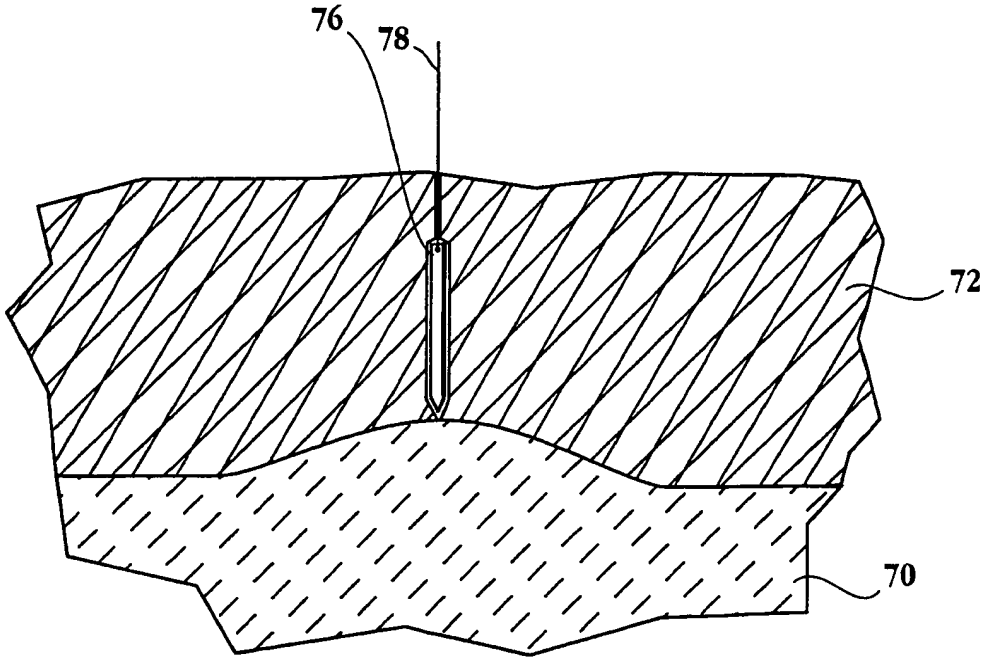

Fig. 6B

INTERNATIONAL SEARCH REPORT

Internatic nl Application No
PCT/US 00/21330

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 665 092 A (LEIBINGER FRANZ ET AL) 9 September 1997 (1997-09-09)	1,2,4,5
A	column 4, line 45 - line 46; figures 1,6,20	3
A	DE 196 47 873 A (DAUM GMBH) 20 May 1998 (1998-05-20) column 1, line 21 - line 25; figure 2	1
A	US 5 258 016 A (CARLOZZI GERARD S ET AL) 2 November 1993 (1993-11-02) column 7, line 2 - line 6; figure 12	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 October 2000	09/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mayer, E

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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